REMARKS/ARGUMENT

Independent Claim 20 has been amended to specify that the particles consist essentially of at least 5 wt% of a low-solubility drug. Support for this amendment is found in paragraph [0023] of published application US 2007/0148232. Claim 20 has also been amended to specify that the particles consist essentially of at least 5 wt% of a poloxamer. Support for this amendment is found in paragraph [0025] of the published application.

New claim 35 has been added, specifying that the amount of drug in the particles is at least 10 wt%. Support for this amendment is found in paragraph [0023] of the published application.

New claim 36 has been added, specifying that the amount of drug in the particles is at least 20 wt%. Support for this amendment is found in paragraph [0023] of the published application.

New claim 37 has been added, specifying that the amount of poloxamer in the particles is 30 to 65 wt%. Support for this amendment is found in the Examples, where the amount of poloxamer in the particles ranges from 30 wt% (Examples 1 and 6) to 65 wt% (Example 7).

Claims 20-29 and 31-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld et al. WO02/089835 (Infield) in view of Babcock et al. EP1027886 (Babcock), the Examiner reasoning that it would have been obvious to add Babcock's HPMCAS to the Infeld composition so as to stabilize the same. Office Action, page 5. Claim 21 has been cancelled, rendering its rejection moot. This rejection is otherwise traversed because there is no suggestion or motivation in either Infeld or Babcock or the two references taken together to add HPMCAS to the Infeld composition.

Infeld discloses a solid unit oral pharmaceutical dosage form of amorphous nelfinavir mesylate and a poloxamer. Page 4, line 20 to page 5, line 22. The solid dosage form is produced by a hot melt granulation process comprising blending the

nelfinavir mesylate and the poloxamer, and heating the blend to a temperature less than the decomposition temperature of the drug. This process results in granules of the drug embedded in the poloxamer. Page 6, lines 8-14. Although other excipients such as stabilizers, wetting agents, binders, disintegrants, diluents and solubizers can be included in the melt granulation, the only examples given are povidone, PEG, and polyoxyethylene sorbitan esters of C_8 - C_{18} fatty acids such as the Tween® series of wetting agents/solubilizers. Page 6, lines 20-25.

An obviousness analysis requires all words of a claim to be considered. *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970). The issue under § 103 is not whether the differences between the claimed invention and the prior art themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp*, 218 USPQ 871 (Fed. Cir. 1983). And an obviousness rejection requires the prior art to provide a suggestion of each claim limitation. *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995); *CFMT v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). Here, independent claim 20 requires that the particles include a stabilizing polymer that is either HPMCAS or CMEC. Applicants note that Infeld does not disclose or suggest that the nelfinavir compositions require any stabilization, let alone stabilization by a cellulosic polymer such as HPMCAS or CMEC. These two facts alone rebut the proposition that one of ordinary skill would be motivated to look to Babcock for a stabilizing polymer.

The Examiner further argues that Babcock shows a solid dispersion of a low-solubility drug and a polymer, contending that the preferred polymer is cellulosic, citing Babcock page 29, lines 19-36, or Babcock claims 1-6. The Examiner appears to have concluded that a cellulosic polymer is preferred because Babcock claim 6 reads, "The composition of claim 1 wherein said polymer is cellulosic." From this, the Examiner seems to reason that, since HPMCAS is a cellulosic polymer, Babcock discloses HPMCAS as a preferred stabilizing polymer for the dispersion. However, the Babcock specification makes it clear that HPMCAS is unsuitable for stabilizing his composition when used alone because it does not satisfy Babcock's glass-transition temperature requirement. Babcock at paragraphs [0057]-[0058]. Note that independent claim 20

recites in subparagraph (c) inclusion of a stabilizing polymer "selected from the group consisting of" HPMCAS and CMEC. The transitional phrase "consisting of" excludes any ingredient not specified in the claim. *In re Gray*, 11 USPQ 255 (CCPA 1931). In other words, claim 20 is limited to inclusion of a polymer that is either HPMCAS alone or CMEC alone. The Examiner argues that, since claim 20 recited "said particles comprising," this opened the claim to the inclusion of stabilizing polymers other than those in the Markush group of HPMCAS and CMEC. Office Action, page 6. But claim 20 has now been amended to recite that the particles "consist essentially of," thereby obviating this reason for maintaining the rejection.

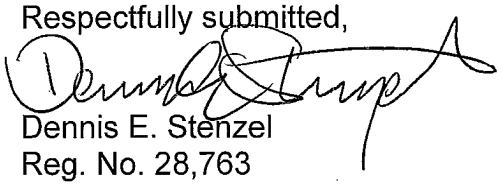
The Examiner further asserts at page 4 of the Office Action that "HPMC will stabilize amorphous low-soluble drugs so that they do not undergo change to crystalline form overtime [*sic*] during storage," citing Babcock at page 3, lines 5-14. But Babcock makes no reference to HPMC or HPMCAS at the place cited, and the undersigned can find no discussion in Babcock that supports the Examiner's assertion.

The Examiner also contends that a preferred exemplary dispersion of Babcock containing HPMCAS is found at page 18, lines 20-25 (Ex. No. 5 in Table 1). However, this dispersion contains equal amounts (67g) of CAP and HPMCAS. The fact that CAP is included with HPMCAS rebuts the Examiner's contention that HPMCAS alone is suggested by the prior art to be suitable as a stabilizing polymer.

For the foregoing reasons, one of ordinary skill in the art would not find it obvious to add HPMCAS to the compositions of Infeld.

Early and favorable reconsideration is respectfully solicited.

Respectfully submitted,



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